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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,936	11/13/2006	Stephen Noel Fitzgerald	C&R-115	5399

23557 7590 08/21/2008  
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EXAMINER
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LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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08/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/573,936

**Applicant(s)**

FITZGERALD ET AL.

**Examiner**

ROBERT LANDSMAN

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 50-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 50-71 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *I. Lack of Unity*

A. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 50 and 71, drawn to a composition of matter.

Group II, claim 51-70, drawn to a method of using a composition of matter.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of claim 1 is a composition of matter consisting of SEQ ID NO:2, or a functional equivalent thereof, which is anticipated by Parham et al. (WO 02/20569). Parham et al. teach a protein 86% identical to SEQ ID NO:2 (see sequence comparison below) of the instant invention. Both the protein of the instant invention and that of Parham are related to TNF. Therefore, the protein of Parham is a functional equivalent of SEQ ID NO:2 of the instant invention. It is also noted that the fact that they both proteins bind an antibody could also make them "functional equivalents". Therefore, Group I lacks novelty or inventive step and does not make a contribution over the prior art.

ID	AAE22289	standard; protein; 250 AA.
XX		
AC	AAE22289;	
XX		
DT	25-JUL-2002	(first entry)
XX		
DE	Human tumour necrosis factor $\alpha$ (TNF $\alpha$ ) protein #2.	
XX		
OS	Homo sapiens.	
XX		
FH	Key	Location/Qualifiers

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FT Misc-difference 1. .22  
 FT /note= "Encoded by ATGG"  
 FT Misc-difference 94  
 FT /note= "Encoded by GC"  
 XX  
 PN WO200220569-A2.  
 XX  
 PD 14-MAR-2002.  
 XX  
 PF 07-SEP-2001; 2001WO-US028013.  
 XX  
 PR 08-SEP-2000; 2000US-0231267P.  
 XX  
 PA (SCHE ) SCHERING CORP.  
 XX  
 PI Parham CL, Gorman DM, Kurata H, Arai N, Sana TR, Mattson JD;  
 PI Murphy EE, Savkoor C, Grein J, Smith KM, Mcclanahan TK;  
 XX  
 DR WPI; 2002-362239/39.  
 DR N-PSDB; AAD35325.  
 XX  
 PT Recombinant polypeptide for immunizing a subject, comprises non-  
 PT overlapping segments of amino acids identical to cytokine receptor  
 PT sequences.  
 XX  
 PS Claim 1; Fig 2; 211pp; English.  
 XX  
 SQ Sequence 250 AA;

Query Match 86.2%; Score 1250; DB 5; Length 250;  
 Best Local Similarity 98.4%; Pred. No. 1.1e-115;  
 Matches 243; Conservative 1; Mismatches 3; Indels 0; Gaps 0;

Qy	36	EAPKPSQASGPEFSDAHMTWLNFRPDDGALRKRCGSRDKKPRDLFGPPGPPGAEVTAE	95
Db	4	EGEEPQASGPEFSDAHMTWLNFRPDDGALRKRCGSRDKKPRDLFGPPGPPGAEVTAE	63
Qy	96	TLLHEFQELLKEATERRRFSGLLDPLLPQAGRLVGEAFHCRLOGPFRVDRKRTLVELHGF	155
Db	64	TLLHEFQELLKEATERRRFSGLLDPLLPQGRGLRVGEAFHCRLOGPFRVDRKRTLVELHGF	123
Qy	156	QAPAAQGAFLRGSGLSLASGRFTAPVSGIFQFSASLHVDHSELQGKARLRARDVVCVLIC	215
Db	124	QAPAAQGAFLRGSGLSLASGRFTAPVSGIFQFSASLHVDHSELQGKARLRARDVVCVLIC	183
Qy	216	IESLCQRHTCLEAVSGLESNSRVFTLQVQGLLQLQAGQYASVFDNGSGAVLTIQAGSSF	275
Db	184	IESLCQRHTCLEAVSGLESNSRVFTLQVQGLLQLQAGQYASVFDNGSGAVLTIQAGSSF	243
Qy	276	SGLLGT 282	
Db	244	SGLLGT 250	

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**2. Further Restriction (this is NOT an election of species). Applicants must elect from either "A" or "B" and, regardless of electing "A" or "B", must also elect from "C"**

**A. Group I**

- (a) a polypeptide
- (b) a nucleic acid, vector and host cell
- (c) a ligand / compound
- (d) a vaccine
- (e) a kit comprising an array; or
- (f) a transgenic animal

**B. Group II**

- (a) a polypeptide
- (b) a nucleic acid, vector and host cell
- (c) a ligand / compound
- (d) a vaccine
- (e) a kit comprising an array; or
- (f) a transgenic animal

***and further elect***

- (a) diagnosing a disease
- (b) treatment and monitoring treatment of a disease
- (c) identification and screening candidate compounds
- (d) diagnosing a disease comprising a mutation (claims 61-63)
- (e) screening candidate compounds using a transgenic animal (claims 69 and 70)

**C. In addition to electing either Group A or Group B, Applicants must also elect –**

one SEQ ID NO corresponding to a protein or one SEQ ID NO corresponding to a nucleic acid. If Applicants elect the protein, the Examiner will examine the fusion protein and will search the nucleic acid encoding the fusion protein. Therefore, Applicants are required to provide a SEQ ID NO for the fusion protein as well as the nucleic acid SEQ ID NO encoding the

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fusion protein if Applicants elect the protein. It is noted that the nucleic acid to the (non-fusion) protein itself will not be examined if the protein is elected.

### 3. *Species Election*

A. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

**Group II - one disease from claims 53, 64, 66 or 68.**

The following claim(s) are generic: claim 51.

### 4. *Rejoinder*

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

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Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/  
Primary Examiner, Art Unit 1647